DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0548]

Proposed Information Collection Activity; Tribal Budget and Narrative Justification Template

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to renew the collection of expenditure estimate forms for the tribal child support program through an optional financial reporting form, Tribal Budget and Narrative Justification Template (Office of Management and Budget #: 0970–0548; expiration date May 31, 2026). Minor changes are proposed. OCSE does not plan to renew either the Word version or the Excel 1115 Waiver version of the Tribal Budget and Narrative Justification Template.

DATES: Comments due April 13, 2026.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: To receive child support funding under 45 CFR part 309, tribes and tribal organizations must submit the financial forms described in 45 CFR 309.130(b) and other forms as the Secretary may designate, due no later than August 1 annually. This optional template is designed for tribes operating an approved tribal child support program to use in preparing their annual budget and narrative justification estimates in accordance with the tribal child support enforcement regulations. The optional Tribal Budget and Narrative Justification Template helps improve efficiency and establish uniformity and consistency in the annual budget submission and review process. Tribes may use the Excel template or their own format to submit the required financial information.

OCSE has made minor revisions to the Excel template by updating citations and hyperlinks from 45 CFR part 75 to 2 CFR part 200. Other changes include edits to examples in the Excel sample budget to reflect the adoption of 2 CFR part 200 and updated formula errors in the Excel document. OCSE proposes to discontinue the Word template since it is not used.

Respondents: Tribes and Tribal Organizations administering a tribal child support program under title IV–D of the Social Security Act.

Annual Burden Estimates

Burden estimates are for all tribes to provide budget information, as required, using either the ACF provided template or their own format.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal Budget and Narrative Justification	63	1	16	1,008

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 45 CFR 309.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–02663 Filed 2–10–26; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0302]

Butylated Hydroxyanisole (BHA); Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information on the current uses and safety data of butylated hydroxyanisole (BHA) in human food and as a food contact substance. We are requesting this information as part of our systematic process for conducting post-market assessments of chemicals in food. We are conducting a post-market assessment of the safety of BHA in food, considering the latest state of the science. We intend to use the information received and any other available, relevant information to determine if BHA remains safe under its current conditions of use in food and as a food contact substance.

DATES: Either electronic or written comments and scientific data and information on the notice must be submitted by April 13, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 13, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–0302 for ''Butylated hydroxyanisole (BHA); Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jason Downey, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–9241; or Barbara Little, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting information on the current uses and safety data for butylated hydroxyanisole (BHA) in human food and as a food contact substance as part of a post-market assessment. BHA (CAS No. 25013–16–5) is used as an antioxidant in food to prevent the spoilage of fats and oils. BHA used in food is a mixture of predominantly 3-*tert*-butyl-4-hydroxyanisole (3–BHA, CAS No. 121–00–6), with varying amounts of 2-*tert*-butyl-4-hydroxyanisole (2–BHA, CAS No. 88–32–4).

All uses of BHA in food or as a food contact substance must be authorized for that use through a food additive regulation or an effective food contact notification, or be excluded from regulation as a food additive, for example, because such use is generally recognized as safe (GRAS) or is prior sanctioned (see Sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act). As described below, BHA is authorized for use in food and as a food contact substance in the U.S. through multiple regulatory pathways.

FDA lists BHA as GRAS for use as an antioxidant in food generally, with the limitation that the total antioxidant content cannot exceed 0.02% of the total fat or oil content of the food (21 CFR 182.3169) (these uses also appear to be the subject of uncodified prior sanctions (see Ref. 1)). FDA also lists this antioxidant use of BHA as GRAS in food for animals (21 CFR 582.3169); however, the focus of our post-market assessment of BHA is on its safety for use in human food. BHA has prior-sanctioned uses as an antioxidant when migrating from food packaging material with a limit of addition to food of 0.005% (21 CFR 181.24). We are not aware of any other GRAS conclusions or prior sanctions for the use of BHA in food or as a food contact substance.

BHA is authorized as a direct food additive when used as an antioxidant, alone or in combination with butylated hydroxytoluene (BHT), in certain foods with specified limitations (21 CFR 172.110). BHA is also permitted as a direct food additive when used as an antioxidant in flavoring substances such that it does not exceed 0.5% of the essential oil content of the flavoring substance (21 CFR 172.515(d)) and as a direct food additive in chewing gum base when used as an antioxidant, alone or in combination with BHT or propyl gallate, such that the total antioxidant content does not exceed 0.1% of the gum base (21 CFR 172.615(a)).

BHA is authorized as an indirect or secondary direct food additive or a constituent of food additives for use as an antioxidant in food contact materials, including in defoaming agents for processing beet sugar and yeast, such that the total antioxidant content does not exceed 0.1% by weight of defoamer (21 CFR 173.340(a)(3)); adhesives (21 CFR 175.105(c)); pressure sensitive adhesives in labels and/or tapes applied to poultry, dry food, and processed, frozen, dried, partially dehydrated fruits or vegetables, or raw fruit or vegetables (21 CFR 175.125(a)(4), (b)(2)); coatings (21 CFR 175.300(b)(3)(xxx), 175.380(a), 175.390(b)(2)); defoaming agents used in the manufacturer of paper and paperboard, including those in contact with aqueous and fatty foods (21 CFR 176.210(d)(3), 176.170(a)(4)); semirigid and rigid acrylic and modified acrylic plastics (21 CFR 177.1010(a)(5)); closures with sealing gaskets for food containers (177.1210(b)); ethylene-vinyl acetate copolymers (21 CFR 177.1350(a)(1)(iii)); defoaming agents used as optional adjuvants in the production of animal glue (21 CFR 178.3120(d)(3)); machinery lubricants

with incidental food contact (21 CFR 178.3570(a)(3)); and polyethylene film, such that it does not exceed 1% by weight of polyethylene polymer and such that the film is not subjected to a dose of radiation exceeding 60 kilograys by gamma, electron beam, or X-radiation (21 CFR 179.45(d)(2)(i)).

We also note that BHA is listed for use in the United States Department of Agriculture (USDA)'s specifications for butteroil (7 CFR 58.305(b)) and USDA's and FDA's standards of identity for margarine (9 CFR 319.700(b)(6), 21 CFR 166.110(b)(5)). The uses are within the scope of the GRAS regulation at 21 CFR 182.3169.

As part of our systematic review of chemicals in food, FDA is beginning a post-market assessment of the safety of BHA as used in food and as a food contact substance (see *https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review*). This assessment supports the Make America Healthy Again Commission's recommendation to implement an evidence-based systematic process for post-market assessment of chemicals in food (see *https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf*). The objective of our assessment is to determine if BHA is safe under its conditions of use in food or as a food contact substance considering the latest state of the science. While FDA previously concluded the authorized uses to be safe, new information may require reconsideration of the regulatory status or the safe uses of a substance in or on food.

II. Request for Information

FDA is requesting information on uses, use levels, dietary exposure, and safety data on BHA currently used in food and as a food contact substance. Information from food manufacturers on uses and levels is crucial for food chemical assessments. We encourage food manufacturers to participate in this data call, with options for aggregated submissions through trade groups or other collaborations. We do not need information about individual products and their recipes, but rather data about the levels of use in general product categories. Voluntary submission of data and information on current uses and use levels will help to refine our dietary exposure assessments. We use maximizing assumptions to estimate dietary exposure (see, *e.g.,* ''Guidance for Industry: Estimating Dietary Intake of Substances in Food,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food*). Without refinements assisted by manufacturer-use information, this may lead to overestimation of dietary exposure that could impact authorizations for the chemical's use in food or as a food contact substance.

Specifically, FDA requests the following:

1. General food categories in which BHA is used (for example, cookies, soft drinks, other categories listed in 21 CFR 170.3(n), USDA's What We Eat in America survey (Ref. 2), or the Codex General Standard for Food Additives (Ref. 3)).;
2. Typical and maximum use levels of BHA in each applicable general food category;
3. Information on the current food contact uses of BHA, including data on migration of BHA from food contact materials into food;
4. Subpopulations with high BHA dietary exposure or particular safety concerns relevant to food and food contact uses of BHA;
5. Other dietary sources of BHA, such as dietary supplements, natural occurrence in common foods, residues in animal products, or as contaminants in food or drinking water;
6. Market share of foods in each applicable general food category and food contact materials that are formulated with BHA;
7. Biomonitoring data for BHA or its metabolites;
8. Updated market disappearance or poundage data for BHA;
9. Information on potential chemically or pharmacologically related substances used in food or as food contact substances;
10. Safety data relevant to use of BHA in food or as a food contact substance, especially unpublished data;
11. Documentation of GRAS conclusions or prior sanctions for uses of BHA in food or as a food contact substance that are different from those described above;
12. Information that may support the conclusion that BHA is no longer used for one or more of its authorized intended uses in food or as a food contact substance.

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Citizen Petition from Roger D. Middlekauff, dated January 23, 1987, available at *regulations.gov* in Docket No. FDA–2026–N–0302.
2. What We Eat in America Food Categories, available at *https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/dmr-food-categories/.*
3. Codex General Standard for Food Additives, available at *https://www.fao.org/gsfaonline/foods/index.html.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5706]

Voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a limited number of drug manufacturing establishments to participate in the third year of the voluntary Quality Management Maturity (QMM) Prototype Assessment Protocol Evaluation Program. The Center for Drug Evaluation and Research (CDER) is implementing this voluntary program for manufacturers of CDER-regulated drug products to gain additional experience with the assessment tool and process. The continuation of this voluntary program is needed to assure that these assessments enable consistent and meaningful evaluations of establishments' quality management practices and provide useful feedback for the establishments. This notice outlines the types of establishments FDA is seeking for participation and the process for submitting a request to participate in the program.

DATES: FDA intends to accept requests to participate in the voluntary QMM Prototype Assessment Protocol Evaluation Program through April 13, 2026. See the ''Participation'' section of this document for instructions on submitting a request to participate and for information about the selection process.